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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/254,563	03/05/1999	VICTOR BRONSHTEIN	UPTINC.015A	7197

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EXAMINER	
SAUCIER, SANDRA E	
ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 12/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/254,563	BRONSHTEIN, VICTOR	
	Examiner	Art Unit	
	Sandra Saucier	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 October 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-10,12-16,25 and 26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-10,12-16,25 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 4-10, 12-16, 25 and 26 are pending and are considered on the merits.

Claim Rejections - 35 USC § 112

Claims 1, 4-10, 12-16, 25 and 26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Insertion of the limitations "above -80°C" and "0°C or above" have no support in the as-filed specification. The insertion of this limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus which would show possession of the concepts. This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Please point to the location in the specification where literal support exists for this recitation or remove it.

Insertion of the phrase "without freezing (ice formation)" does not appear to have literal support in the generic portion of the specification. Because the specification does not have a working example, no support can be found in an example. Further, neither the originally filed claims nor the abstract provide support for this recitation

Applicant argues that "vitrifying" is not new matter because one of skill in the art would understand that it is inherent in the specification. This argument is not particularly persuasive. However, upon rereading the specification, the Field of Invention on page 1 states that "This invention relates to ... solutions,

as well as ***vitrification and rehydration procedures***.". Thus, upon reconsideration, this element is not considered to be new matter.

When making an amendment to a pending claim, please point to the exact place in the specification where support is found for a new recitation.

Applicant is hereby notified that the insertion of new matter into the claims has necessitated the removal of art rejections over the claims. However, removal of new matter may result in the reinstatement of the art rejections.

INDEFINITE

Claim 1, 4-10, 12-16, 25 and 26 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, step (a), the term "concentrated" is used. Concentrated is a term of comparison without a reference point and is, therefore, without distinct metes and bounds. Thus, the claim is indefinite.

Claim 1 has parenthetical insertions which may or may not be intended to further limits the claim. Thus, the use of such insertions renders the claims indefinite.

Claim Rejections - 35 USC § 102

Claims 1, 4-7, 9, 10, 12-16, 25 and 26 remain rejected under 35 U.S.C. 102(e) as being clearly anticipated by US 5,800,978 [E].

The claims are directed to a method of preserving cells or tissue by equilibrating and dehydrating a cell or tissue with a solution comprising a

1) non-permeating co-solute (amino acids or derivatives, betaine, carbohydrate such as {aldose monosaccharide, ketose monosaccharide, amino

sugar, alditol, inositol, aidonic, uronic or aldaric acid}, a sugar alcohol, disaccharide or polysaccharide),

2) a permeating cryoprotectant (DMSO, ethylene glycol, propylene glycol or glycerol) and

3) a non-permeating polymeric cryoprotectant (dextran, starch, PEG, PVP, Ficoll, peptides),

vitrifying the specimen by cooling to a refrigeration temperature above -80°C, and rehydrating and unloading the specimen after storage and warming to 0°C or above.

US 5800978 discloses a cryopreservation medium comprising 0.5M glycerol, 7.5% BSA and 0.3M glucose or 5% glucose, 10% FCS, 20% Dextran 40 (Table 1). A method of cryopreservation or red cells using 5% glucose (permeant), 10% sucrose (impermeant) and 20% PVP (impermeant) (buffer #8 Table 2) and other three component combinations of cryoprotectants is shown. The general principle of using a three component cryoprotectant buffer comprising a permeant (monosaccharides or polyalcohols), impermeant (disaccharide) and a high molecular weight polymer is disclosed in Example 1. Example 1 also states that the Tg of the solution MUST BE ADJUSTED to that the Tg exceeds -45C and preferably is above -25C for convenient frozen storage.

In example 4, 5.7 mls of cryoprotectant buffer was added to 5 mls of cells in dextrose-saline then an additional 5.7 mls of buffer was added prior to lowering the temperature to -80C. This is a one step increase in concentration of the buffer prior to lowering the temperature. During thawing, the cells were reconstituted by dilution of the freezing buffer with a reconstitution buffer comprising PVP and glucose (example 4). In table 11, red cells after dehydration are stored at 80°C for 4-6 days. In Table 10, a mixture of glycerol, glucose, lactose and HES is added to red cells prior to lyophilization.

Applicant argues that the reference discloses "freezing" not vitrification. However, the reference discloses quickly lowering the temperature of the sample to -80C which is below the Tg of the cryoprotectant about -30C. Therefore, the sample is vitrified because the temperature has been lowered below the temperature at which it vitrifies (glass transition temperature, T_g). Whether of not the reference appreciates that the sample is not "frozen" or has used improper language to describe a state which results from the performance of the disclosed steps is of little import. Lowering the temperature of a vitrifiable mixture below its vitrification point results in a vitrified sample whether or not the true state of the sample is appreciated or conveyed in the text.

Applicant argues that the instant invention does not disclose vitrification, but discloses a method "that at appropriate temperatures form partially crystalline mixtures of water ice with interspersed regions of a separate amorphous glass phase". However, since the physical steps disclosed in the prior art are the same physical steps that are performed in the claimed method and use the same permeant and impermeant cryoprotectants in the same concentrations to achieve glass transition points of the specimen which are above the temperatures to which the specimens are cooled, and as vitrification is a result of the lowering of the temperature of the specimen below the glass transition temperature, the results of the method disclosed in the prior art are reasonably assumed to be the same as the results that are in the pending claims. Whether applicant or cited prior art achieves the state of matter that they anticipate or claim has not been demonstrated.

Applicant continues to state that US '978 does not teach vitrification but freezing. Please see US '978, col. 5, ln. 35 where a discussion of amorphous glass formation useful for cryostabilization of products is presented. Arguments directed to intended results absent physical parameters or steps which differentiate the claimed method from the disclosed method, while interesting, are not probative.

"To invalidate a patent by anticipation, a prior art reference normally needs to disclose each and every limitation of the claim. See Standard Havens Prods., Inc. v. Gencor Indus., Inc., 953 F.2d 1360, 1369, 21 USPQ2d 1321, 1328 (Fed. Cir. 1991). However, a prior art reference may anticipate when the claim limitation or limitations not expressly found in that reference are nonetheless inherent in it. See id.; Verdegaal Bros., Inc. v. Union Oil Co. of Cal., 814 F.2d 628, 630, 2 USPQ2d 1051,1053 (Fed. Cir. 1987). Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates. See *In re* King, 801 F.2d 1324, 1326, 231 USPQ 136, 138 (Fed. Cir. 1986). Inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art. See Titanium Metals, 778 F.2d at 780. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art. See id. at 782. However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. See id. at 782 ("Congress has not seen fit to permit the patenting of an old [composition], known to others . . . , by one who has discovered its . . . useful properties."); Verdegaal Bros., 814 F.2d at 633.

This court's decision in Titanium Metals illustrates these principles. See Titanium Metals, 778 F.2d at 775. In Titanium Metals, the patent applicants sought a patent for a titanium alloy containing various ranges of nickel, molybdenum, iron, and titanium. The claims also required that the alloy be "characterized by good corrosion resistance in hot brine environments." Titanium Metals, 778 F.2d at 776. A prior art reference disclosed a titanium alloy falling within the claimed ranges, but did not disclose any corrosion-resistant properties. This court affirmed a decision of the PTO Board of Appeals finding the claimed invention unpatentable as anticipated. This court concluded that the claimed alloy was not novel, noting that "it is immaterial, on the issue of their novelty, what inherent properties the alloys have or whether these applicants discovered certain inherent properties." Id. at 782. This same reasoning holds true when it is not a property, but an ingredient, which is

inherently contained in the prior art. The public remains free to make, use, or sell prior art compositions or processes, regardless of whether or not they understand their complete makeup or the underlying scientific principles which allow them to operate. The doctrine of anticipation by inherency, among other doctrines, enforces that basic principle." See Atlas Powder Co. v. IRECO Inc. 51 USPQ2d 1943 (Fed. Cir. 1999).

Thus, a reference may be anticipatory if it discloses every limitation of the claimed invention either explicitly or inherently. A reference includes an inherent characteristic if that characteristic is the "natural result" flowing from the reference's explicitly explicated limitations. Continental Can Co. USA, Inc. v. Monsanto Co., 948 F.2d 1264, 1269, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991).

In the instant case, the vitrification of the sample flows from the use of a vitrifiable solution containing the sample with a glass transition temperature which is higher than the storage temperature. Thus applicant is incorrect in arguing that the anticipatory rejection is improper.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In

no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday, Tuesday, Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sandra Saucier
Primary Examiner
Art Unit 1651
December 19, 2005